CURRICULUM VITAE

Dieter E. Herten

Dieter Herten CATADIA Consulting - Pharmaceutical & Medical Devices Industries is the service-orientated consulting partner for Quality Management and Compliance Management.

The focus of my expertise is GxP-Compliance Consulting for the Pharmaceutical Industry (21CFR Part 210/211 Drug GMPs; FDA), Medical Devices (ISO 13845; ISO 14971; IVD, MPG), AMG and EU-Guidline 2001/20/EC (IMPD).

My service includes: GxP-Compliance Audit & Study, GAP-Analysis, Conception and (Re)Design of Quality Management Systems (QMS), Service Management (ITIL), Service Level Agreements (SLA), Risk Management, Change Management & Control and Project Management and Coaching. Computer System Validation (CSV), Equipment and Infrastructure Qualification,

For over 23 years my work experience guarantees a professional and excellent service for the top companies of the pharmaceutical, medical device and supplier industry (Audit, conceptual, operational and coaching).

Career Details

Person Detail	
Name	Dieter E. Herten
Address	Jentgesallee 11, 47799 Krefeld, Germany
Phone	+49-2151-1518001 +49-171-2061155
Education	
University	Study of Physics and Engineering at the University Düsseldorf and GHS University Essen; Degree: Dipl.-Physic-Engineer
Professional Experience	
1992 – to date	Founder and managing director of Dieter Herten CATADIA Consulting Pharmaceutical & Medical Devices Industries; Krefeld, Germany (former CATADIA Consulting GmbH)
1989 – 1991	Director, Gruber Tietze & Partner GmbH BfIM, Bad Homburg, Germany
1988 – 1989	Senior Consultant, Gruber Tietze & Partner GmbH BfIM, Bad Homburg, Germany
1987 – 1988	Consultant, DETELKOM GmbH, Frankfurt/M
1985 – 1987	Consultant, PA Computer & Telecommunication Ltd., London, UK
1982 – 1985	Sales & Marketing, AEG Olympia Werke AG Frankfurt/M & Wilhelmshaven, Germany
Language Skills	
German	Native
Englisch	Business fluent

Technical Skills

MS-Office; MS-Project, MS-VISIO; IDS ARIS, AGILE (User Knowledge); PLA 2.1; FMEA Excel Tool

References: Pharma and Medical Devices

Branche/Client	Theme	In short
07.2015 KWST, Germany	GMP QMS Concept	Development of a concept to become GMP compliant.
08.14 – 06.2015 Dako, Denmark	QA-Support GxP-Audits GAP-Analysis Risk Management (FE-MA); Support NCR and Com-plaint Handling and Coaching CSV, Equipment Valida-tion, ,	Performance of several GMP Compliance Studies GMP Audits & Studies (FDA-Inspection preparation) Support of the FMEA Risk Method & Performance Instrument validation risk assessments Equipment Qualification CSV- Projects, Excel validation activities Coaching of project teams in validation All activities were part of a FDA-Compliance Remedia-tion project.
Food Industry 01-07.2014	Support Company Acquisition	Due Diligence Market & Production Risk Management Evaluations Financial Cost / Profit Calculations HACCP & IFS Evaluation Acquisition Negotiation Support
Johnson & Johnson Depuy Synthes 2013	Performing Compliance Analysis and Legacy CSV Reviews for IT-Applications. Basis: ISO 13845, MPG Work System: AGILE e6.1	Performing Compliance Risk Analysis (FMEA, etc) GxP-Audits Performance Legacy CSV Reviews Change status control in the Agile System Evaluation of the IT-Applications for a central IT-Inventory GxP Coaching of a production site
AOP ORPHAN 2012 – 2013	CSV and Risk Manage-ment of all IT-Systems Coaching	Master Validation Plan Risk Management (FMEA) GxP Compliance GAP-Analysis CSV-SOP CSV of IT-Systems (Infrastructure, Applications) Coaching of project members
Bayer Technology 2012 - 2013	Concept & Process Design for a new IT-System De-velopment System incl. CSV	Study about Annex-11 status of the existing IT-Development System New Design (Concept and processes incl. all templates and best practices) of the IT-Development System incl. CSV following GAMP-5, Risk Management (FMEA, other) and Service Management (ITIL) inkl. SLA This includes also Change Management & Control pro-cesses.

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Bayer, Bausch & Lomb, Grünenthal, Novartis, HEXAL , Hoechst, Roche, Sanofi, Pfizer, SANDOZ, Schering 1992 - 2013	Pharma GxP-Consulting	No. of projects from the consulting areas: QM-System Development / Re-Design, Risk Management (FMEA, NCR, CAPA, Complaint Handling) GxP-Audits (intern/extern) GxP-Compliance Studies GxP-GAP-Analysis Computer System Validation (CSV) Equipment-/Infrastructure- Qualification Coaching IT-Service-Management (ITIL) Service Level Agreements (SLA) IT-Development Process (GAMP 5 related) Change Management & Control Project Management & Quality Management
Straumann 2008	Computer System Validation	Relocation Waldenburg / Basel
1994 – 1996	IT-Project Management and QS for the new warehouse and packaging center Kaiseraugst, Swiss	IT-Project Management Validation Master Plan Infrastructure Qualification Equipment Qualification Computer System Validation
F. Hoffmann-La Roche 1992 - 1993	Relocation Data Center	Planning and Project Management of the relocation of the data center from Basel to Kaiseraugst

Beside these industries I have performed a number of projects for Daimler, Telekom and Haefele.

Extracurricular Activities

ISPE	Since 1992
Rotary International	Member of the board, Foundation and social projects

Interests

Family, Tennis and Running